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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,043	10/25/2000	Eino Elias Hakalehto	933-162P	3800

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,043

Applicant(s)

HAKALEHTO, EINO ELIAS

Examiner

Patricia A. Duffy

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 19, 20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17, 19, 20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed 6-1-05 has been entered into the record. Claims 14-17, 19, 20, and 22-23 are pending and under examination.

The examiner in charge of this Application has changed. Please address all future correspondence to Exr. Patricia A. Duffy, Art Unit 1645.

All the previous rejections of record are withdrawn in view of the new grounds of rejection set forth below.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings in this application have been approved. No further action is required by Applicants.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a written description rejection.

As to claims 14-16, 22 and 23, the claims recite detection of fimbral antigens. Claim 17 further limits the detection to fimbral antigens that are proteins. The teachings of the specification are limited to immunological detection of Type 1 fimbriae protein antigen bound by an antibody raised to the peptide of SEQ ID NO:1. The specification fails to disclose or describe detection of fimbral antigens that are not proteins or polypeptides. The specification fails to describe appropriate non-protein fimbral antigenic structures or other non-protein fimbrial structures that can be detected and the means of detection of such. The specification fails to point to the art to these other structures and how to detect these non-protein fimbral antigens as claimed by either classical or immunological means. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

Claims 14-17, 19, 20, and 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for , does not reasonably provide

enablement for a rapid method of detecting *Salmonella* spp. having Type I fimbriae, comprising inoculating a sample into selective Rappaport-vassiliadis soya peptone broth to form an incubation mixture, incubating the mixture for a time period of 3-10 hours under conditions of aerobic shaking and within a time period of 3 to 10 hours from the onset of inoculation detecting Type I fimbriae antigens during the incubation time period wherein the time period is before an actual logarithmic growth phase of the *Salmonella* or in the beginning of the logarithmic growth phase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The teachings of the specification are limited to detection of Type I protein fimbrial antigens in *Salmonella* using specific incubation conditions, media and temperature. (see Examples 1-5 and Figures 1 and 2), none of which is specifically set forth in the claims. The art teach that *E. coli* and other enteric microorganisms can express many types of external appendages known as fimbriae, a term that is used interchangeably with pili. Which appendages are produced under a given condition depends on an astonishing variety of regulatory mechanisms (Annual Review of Microbiology, 49:747-75, 1995). *E. coli* have at least two other fimbriae (P and S) that are differentially regulated as compared to Type I fimbriae. Tavendale et al (Medical Microbiology, infections disease, virology, parasitology. 261(2):240-7, April 1986) teach that several infantile enteropathogenic serotypes produced Type I fimbriae after serial growth in nutrient broth, in phosphate buffered broth but not in nutrient broth or after growth on phosphate buffered agar (see abstract). Gander et al (Infection and Immunity, 55(2):293-297, 1987) teach that the expression of different types of pili/fimbriae are markedly influenced between the same cells grown under different conditions and different temperatures (see abstract). Payne et al (Journal of Immunological Methods. 159(1-2):283-289, 1993) teach that the expression of K88 fimbrial adhesion antigen was differentially expressed with respect to different media types and forms. Further, under

unshaken batch culture there was correlation between growth phase and expression, where maximal concentrations detected during late log to early stationary phase and that the control was quantitative and not qualitative (see page 34, abstract). Van Der Woudek et al (Journal of General Microbiology, 135(12):3421-3430, 1989) teach that the amount of fimbriae produced by P+ fimbriate *E. coli* cells is dependent upon the specific growth rate and the at the composition of the growth medium influenced both the phase variation and overall production of fimbriae and shifts from minimal to complex medium rapidly reduced the amount of fimbriae per cell (see abstract).. Van Versveld et al (Infection and Immunity, 49(1):159-163, 1985) teach that the production of two different fimbral adhesions K99 and F41, was significantly affected by the external pH of the medium over a narrow range. Further VanVersveld et al teach that a significant production of fimbriae was only detected at μ values higher than 0.2h^{-1} . Isaacson (Infection and Immunity, 40(2):633-639, 1983) teaches that the addition of L-alanine to minimal medium inhibited K99 pilus production and in contrast to other reports, the addition of glucose did not affect K99 pilus assembly or subunit synthesis. Burman (Journal of Bacteriology, 123(1):265-71, 1975) teaches that under the same incubation conditions the F-pilus is differently regulated and expressed as compared to the I-type pilus in *E. coli*. (see abstract). Xie et al (Infection and Immunity, 65(6):2265-2271, 1997) teach that the expression of fimbrillin, the major subunit protein of the fimbriae, in *Porphyromonas gingivalis* is differently affected by incubation temperature, hemin limitation and culture on solid medium and concludes that the gene is regulated at the transcriptional level in response to several environmental conditions. Daigle et al (Microbial Pathogenesis, 22:247-252, 1997) teach the effect of growth conditions on the expression of F1651 fimbriae in *E. coli*. Daigle et al teach that the expression of F1651 fimbriae is negatively regulated by glucose, leucine, alanine to media, growth at 18°C and pH above or below 7.0. As such, the plethora of evidence presented indicate that different fimbriae/pili are differently regulated in different microorganisms and the regulation of each is subject to

separate environmental , growth regulatory or phase variation controls. As such, the skilled artisan could not extrapolate from the limited example in the specification to expression and detection of other pili/fimbriae in other microorganisms grown or enriched under different incubation or cultivation conditions. As such, the teachings of the specification are insufficient to enable the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-17 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Issacson et al (Infection and Immunity, 40(2):633-639, 1983).

Issacson et al teach the production of K99 pilus in *E. coli*. Issacson et al teach the detection of K99 on the surface of *E. coli* cells at 3 hours from the onset of cultivation (see page 634, Figure 1). K99 was detected using an antibody assay (see page 633, column 2, K99 assays). Under the incubation conditions it appears that the K99 pilus was measured in "early log phase". As such, the method of the prior art meets all the limitations of the instantly claimed invention.

Claims 14-17 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Payne et al (Journal of Immunological Methods, 159:283-289, 1993).

Payne et al teach the production of K88 fimbrial antigen in *E. coli*. Payne et al teach the detection of K88 on the surface of *E. coli* cells between 6 and 12 hours from the onset of cultivation (see page 287, Figure 1, Legend; "B" and "C"). K99 was detected using an antibody assay (see pages 284-285, bridging paragraph). Under the incubation conditions the K88 pilus was measured before and during "early log phase". As such, the method of the prior art meets all the limitations of the instantly claimed invention.

Status of the Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 09/646,043

Page 8

Art Unit: 1645

Patricia A. Duffy

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645